JUL 0 6 2000

K001789

7.0 Premarket Notification 510(k) Summary

Submitter

W. L. Gore and Associates, Inc
P.O. Box 500
Flagstaff, AZ 86002-0500

Date Prepared: June 26, 2000

Contact: R. Larry Pratt
520-779-2771

Applicant Device

SEAMGUARD® Staple Line Reinforcement Material

Applicant Device Indication For Use

The device is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using linear surgical staplers.

The device is indicated for use in the buttressing and reinforcing of staple lines during lung resections (e.g., wedge resections, blebectomies, lobectomies, bullectomies, bronchial resections, segmentectomies, pneumonectomies, pneumoreduction, pneumectomies) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. The device can also be used for abdominal and thoracic wall repairs, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical). The device can be used with anastomotic staplers or with non-anastomotic staplers.

Predicate Device

Peri-Strips® Staple Line Reinforcement and SEAMGUARD® Staple Line Reinforcement Material are cited as predicate devices which have been found to be substantially equivalent through the premarket notification process.

Technological Characteristics

This Premarket Notification concerns only the modification of the indication statement. Consequently, the applicant device is the same as the predicate SEAMGUARD® Staple Line Reinforcement Material with regard to design, composition, manufacturing, blood and tissue compatibility, packaging, mechanical strength, quality characteristics and sterilization process.

The applicant device has the same intended use and the same indications as the predicate Peri-Strips® Staple Line Reinforcement device.

Clinical experience information contained in the published literature (50 patients, one year period) demonstrate the ePTFE based applicant device will fulfill its clinical function both safely and effectively.

Safety and Effectiveness Conclusions

The applicant SEAMGUARD® Staple Line Reinforcement Material is substantially equivalent to the predicate Peri-Strips® Staple Line Reinforcement device with regard to intended use and indications. Both devices fulfill their equivalent clinical functions by buttressing and reinforcing staple lines.

The applicant device is substantially equivalent to the predicate SEAMGUARD® Staple Line Reinforcement Material with regard to device design, composition, manufacturing, blood and tissue compatibility, packaging, mechanical strength, quality characteristics, and sterilization processes. The devices are the same except for the added indication statement.

The referenced and descriptive information and data contained within this Premarket Notification submission are sufficient to demonstrate substantial equivalence of the applicant device to the predicate devices. There are no patient safety concerns raised as a result of the clearance of the applicant device.

SEAMGUARD® is a trademark of W.L. Gore and Associates, Inc.

Peri-Strips® is a trademark of Bio-Vascular, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 6 2000

Mr. R. Larry Pratt
Regulatory Affairs
W. L. Gore & Associates, Inc.
Medical Products Division
3450 West Kiltie Lane
Flagstaff, Arizona 86002

Re: K001789
Trade Name: Seamguard Staple Line Reinforcement Material
Regulatory Class: II
Product Code: FTL
Dated: June 12, 2000
Received: June 13, 2000

Dear Mr. Pratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001789

Device Name: SEAMGUARD Staple Line Reinforcement Material

Indications For Use:

SEAMGUARD® Staple Line Reinforcement Material is intended for use as a prosthesis for surgical repair of soft tissue deficiencies using linear surgical staplers. The device is indicated for use in the buttressing and reinforcing of staple lines during lung resections (e.g., wedge resections, blebectomies, lobectomies, bullectomies, bronchial resections, segmentectomies, pneumonectomies, pneumoreduction, pneumectomies) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. The device can also be used for abdominal and thoracic wall repairs, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical). The device can be used with anastomotic staplers or with non-anastomotic staplers.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001789

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)